REMARKS

This paper is responsive to the Office Action dated October 1, 2009. In the Office Action, the Examiner issued a final rejection of all pending claims, namely claims 1-10 and 21-30.

35 USC 103(a) rejections:

Claims 1-10:

Claims 1-10 were rejected under 35 USC 103(a) as being unpatentable over applicant's admitted prior art (AAPA) (specification pages 1-3) in view of van Muiden (EP 0662385).

The prior art referenced by Applicant in the specification is generally discussed in the incorporated-by-reference U.S. Patent No. 5,380,304. As described therein, multi-layer introducer sheaths commonly utilized in the art are generally constructed by placing an inner liner material over a mandrel, positioning a braid or a coil over the outer surface of the inner liner, and positioning an outer thermoplastic material over the braid or coil. The assembly is placed in a heat shrink enclosure, and baked in oven to cause the thermoplastic outer layer to melt and flow between the wires of the braid or coil, such that it bonds to the outer surface of the inner liner.

Generally, it is desirable to maintain the wall thickness of an introducer sheath as small as possible. In this manner, the largest possible device can be passed into a body vessel through the smallest possible entry hole. Although the coil-reinforced prior art device (AAPA) referenced in the Background of the present application has a relatively thin wall, medical device designers are constantly searching for ways to reduce the wall thickness even more. In addition, as further stated in the Background (paragraph [0005]), on some occasions it is desirable to incorporate both a braid and a coil reinforcement into a sheath, and yet maintain a low sheath profile. (paragraph [0023]).

Those skilled in the art recognize that a braid is typically utilized to enhance torque control, whereas a coil is typically utilized to enhance the kink resistance of the sheath. (paragraph [0003]). Combining these two reinforcements in a single

sheath provides enhancements to both torqueability and kink resistance. However, utilizing both reinforcements in an intermediate layer results in a structure that may be more thick-walled than desired, which wall thickness may preclude use of the sheath in some instances. In addition, when the two reinforcements are combined in a single sheath, the wire or monofilament layers are susceptible to interfering with each other. When this occurs, the resulting device may have neither good torqueability nor good kink resistance. (paragraph [0005]).

The present application addresses the problems of providing a sheath having as thin a wall as possible. The application also addresses problems encountered when constructing a sheath having the beneficial features provided by each of a coil (kink resistance) and a braid (torqueability).

Claim 1 is directed to a method of manufacturing an introducer sheath. Claims 2-10 depend therefrom. These claims add additional limitations, including incorporating a coil into the sheath (claims 8 and 9). Generally speaking, claim 1 includes the steps of positioning a first polymeric sleeve over a mandrel, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along the first sleeve; positioning a second polymeric sleeve over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve, the first and second polymeric sleeves being axially aligned such that the second striped extrusion is superposed over the first striped extrusion to define a generally braid-like configuration; and heating the first and second polymeric sleeves.

According to the Examiner, AAPA teaches positioning a sleeve over a mandrel and heating the mandrel. However, the Examiner has acknowledged that AAPA does not teach multiple sleeves with helical stripes. As such, the feature of incorporating a braid into a sheath in this manner is not derivable from AAPA.

Van Muiden was cited for allegedly teaching a method wherein a first sleeve with a striped helical pattern was positioned over a mandrel, and a second sleeve with a striped helical pattern was positioned over the first sleeve to define a braid-like configuration. According to the portions of van Muiden referenced in support of the

rejection, an extrusion profile 30 is made up of two coaxial layers 31, 32, each having a number of extruded helically shaped bands of material. The bands of material 33 in the outermost layer 31 are running in the opposite direction to the helically shaped bands of material 34 in the innermost layer 32. Upon extrusion, a bond can be formed between the two layers with the helically shaped layers of material formed inside. However, as shown in Fig. 4 of van Muiden, the sheath maintains the integrity of the separate layers 31, 32. Thus, even though van Muiden recognizes the trend toward ever thinner catheters (Col. 1, lines 17-20), in the cited embodiment of Fig. 4, van Muiden maintains two separate layers in order to provide his substitute for a braided reinforcement. This teaches away from the desire to provide a sheath having as small a wall thickness as possible, and to provide the beneficial characteristics achievable with a braid. In fact, a sheath resulting from the claimed combination may not even be useable in some instances in which a smaller diameter sheath is required, much in the same manner as the prior art sheath having both a braid and a coil as referenced in the application.

Unlike either of the cited references, the method of claims 1-10 addresses the problem of providing torque control in a thin-walled sheath by positioning dual polymeric sleeves over a mandrel in the manner described above, and then heating the sleeves as described. The sleeves melt together into an outer layer having the superposed striped extrusions that define the braid. Neither reference teaches or suggests this step. As the Examiner noted, AAPA does not teach such multiple sleeves with helical stripes. Thus, the braid-like feature that provides torqueability to the sheath is not achievable in the low-profile sheath resulting from the prior art method. Similarly, van Muiden does not teach or suggest melting the two outer layers (31, 32) to obtain the low profile that he refers to as a desirable feature. Rather, by maintaining two outer layers, he teaches away from the desirability of providing a sheath having as small a wall thickness as possible.

AAPA teaches that an assembly comprising an inner liner, a reinforcing layer, and an outer layer may be placed in a heat shrink enclosure, and melted therein such that the outer layer bonds to the inner layer through the wires of the reinforcement.

The method of claim 1 eliminates the necessity of positioning the reinforcement over the inner liner. Rather, the second polymeric sleeve is positioned over the first sleeve, and during a heating step, the second striped extrusion (from the second sleeve) is superposed over the first striped extrusion (from the first sleeve), to define the reinforcing member.

Unlike the prior art method, the claimed method does not utilize a discrete reinforcing member. When a reinforcing member as described in the prior art structure is wrapped around the inner liner, the area of the liner covered by the reinforcing member is not otherwise available for bonding with the outer layer. This can result in a sheath in which the bonding between the inner and outer layers is less than desirable. With the design obtained by the inventive method, virtually the entire outer surface of the inner liner is available for bonding with the outer layer, and yet the sheath nonetheless includes a reinforcing member. Thus, not only may a sheath be obtained having a smaller outer diameter, but the sheath may have a stronger bond between the outer and inner layers due to the extra surface area between the two layers available for bonding.

The test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference, but rather, what the combined teachings of the references would have suggested to those of ordinary skill in the art. [legal citations provided in previous response]. Further, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In making a prima facie determination of obviousness, the Examiner should identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Applicant respectfully submits that a prima facie case of obviousness of the present claims in view of the cited combination has not been set forth by the Examiner. Each of the references recognizes the desirability of providing a low

profile sheath having enhanced torqueability and/or kink resistance; however, the references do not teach or suggest the solution to the problem arrived at by the present claims. In fact, although van Muiden includes some features in common with the claimed invention, the cited embodiment maintains dual outer sleeves in a manner that does not advance the desire of maintaining a low wall thickness. Applicant submits that no articulated reasoning with rational underpinning has been provided to support the obviousness finding, as required. Applicant further submits that it is only after the benefit of Applicant's disclosure is gained that the features of the invention may appear to be obvious. Neither of the citations, either individually or in combination, teaches or suggests the manner of incorporating a braid-like configuration into a thin-walled sheath as claimed, nor do they teach or suggest a structure that is capable of enhanced bonding between the inner and outer layers as described.

Claims 21-30:

Claims 21-30 were rejected under 35 USC 103(a) as being unpatentable over Parker (US 5,380,304) in view of van Muiden (EP 0662385). Claims 22-30 depend from independent claim 21, and therefore include all of its limitations. These claims will not be separately considered for purposes of this after final response.

Claim 21 is directed to a method of manufacturing an introducer sheath. An inner liner is positioned over a mandrel, and a coil is positioned over the mandrel. A first polymeric sleeve is positioned over the coil, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along the first sleeve. A second polymeric sleeve is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve. The second striped extrusion has a pitch generally opposite a pitch of the first striped extrusion. The second sleeve is aligned over the first sleeve such that upon a melting of the sleeves the second striped extrusion is superposed over the first striped extrusion, and a generally braid-like configuration is defined thereby. A heat shrink material is positioned over an

assembly comprising the mandrel, inner liner, coil, and first and second sleeves. The assembly is heated to a temperature sufficient to cause the heat shrink material to shrink, wherein the first and second sleeves melt together to form an outer tubular layer and to define the generally braid-like configuration therein, and the heat shrink material causes the outer tubular layer to bond to the inner liner through the coil turns.

The steps of this claim are generally illustrated in the sequence of Fig. 6 of the present application, and discussed in the related portions of the specification. At a minimum, the cited art does not teach or suggest the feature of combining first and second sleeves having respective striped extrusions as described over an inner liner and a coil, and melting the first and second sleeves in a heat shrink enclosure to form an outer tube (e.g., paragraphs [0029] and [0032]). In this manner, a sheath is obtained having the desirable features of 1) a thin wall; 2) enhanced kink resistance (via the coil); and 3) enhanced torqueability (via the braid). Such a sheath is clearly not derivable from the prior art methods referenced by the Examiner, either individually or in combination.

As acknowledged by the Examiner, Parker does not teach the "positioning" steps of the claimed method that involve the arrangement of the two polymeric sleeves. Accordingly, Parker also cannot teach or suggest the "heating" step that causes the first and second "positioned" sleeves to melt together to form the outer tubular layer, and to define the braid-like configuration in that layer. Van Muiden was said to teach a two layer polymer sleeve for a catheter including striped helical patterns for defining a braid-like configuration. Therefore, according to the Examiner, it would have been obvious to substitute the sleeve of Parker with the helical stripes of van Muiden to arrive at the claimed method.

Applicant respectfully submits that the combined disclosures of the cited references fall far short of teaching or suggesting the claimed method. For example, the claimed method provides a sheath having dual reinforcements. Neither reference suggests this feature, nor is it readily derivable from them. Parker teaches a method for forming a sheath having a coil reinforcement in classical fashion. That is, the coil is positioned over the inner liner, and the outer jacket is positioned over the coil and

inner liner. The entire assembly is placed in a heat shrink enclosure, and thereafter heated such that the outer layer bonds to the inner liner through the coil turns.

However, the general method described in the Parker citation is not particularly well-suited for construction of sheaths having dual reinforcements, such as the sheath manufactured by the method of claim 21. As stated in the present application (page 2, lines 11-18), utilizing both reinforcements in an intermediate layer of an otherwise conventional sheath results in a structure that may be too thick-walled for some proposed uses. In addition, the wire or monofilament layers are susceptible to interfering with each other, in which case the resulting device would have neither good torqueability nor good kink resistance. Still further, the presence of dual reinforcing members limits the ability of the outer jacket to bond with the inner liner, by minimizing the amount of surface area of these layers that would otherwise be available for use in formation of a secure bond therebetween.

Van Muiden teaches a structure that mimics the presence of a braid, by providing two side-by-side layers, each having an oppositely-directed helical structure. Van Muiden does not, however, teach or suggest a method in which dual reinforcing members can be incorporated into his sheath, nor does he teach or suggest a melting step for lowering the overall profile of his layers. In order to incorporate a **second** reinforcement (with the additional layers required to do so) according to the teachings of van Muiden, an unreasonably thick-walled structure would result.

According to the claimed method, a sheath is formed utilizing the heat shrink technology of Parker, yet having the benefit of dual reinforcements. Further, the sheath is formed in a manner to avoid the problems of prior art dual reinforcement sheaths discussed in the present application. The Examiner improperly combines Parker with van Muiden in order to allegedly arrive at the claim. Applicant respectfully submits that the combination is improper on numerous grounds. For example, the Examiner seems unconcerned over the fact that neither reference suggests use of the technology taught therein in a sheath having dual reinforcing members. Further, even if such suggestion would have been present, neither reference teaches or suggests adding a second reinforcing member by any means

other than the same method used for the (first) reinforcing member already present in that particular reference. Additionally, even if a suggestion for a second reinforcing member could be found, such combination would be illogical in the context of an introducer sheath as described therein. Such a sheath would either have an unreasonably thick-walled structure, or have less than desirable bonding between the respective layers.

Finally, Applicant respectfully submits that the improper use of hindsight reconstruction is clearly evident in this case. The Examiner has sifted through the teachings of two disparate references to arrive at the claimed method, *neither of which teaches or suggests the concept of combining two reinforcements in a single sheath*, nor suggests any manner in which this can be accomplished while maintaining a thin-walled structure. Absent Applicant's disclosure herein, such combination would not be made by an artisan skilled in this field.

Conclusion:

Based upon the foregoing, Applicant respectfully submits that the grounds for rejection of the claims have been overcome, and that all claims 1-10 and 21-30 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a timely notice of allowance. If the Examiner believes that further prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,

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